

Safety

Recall -- Firm Press Release

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American Regent Initiates Voluntary Recall of Dexamethasone Sodium Phosphate Injection, USP 4 mg/mL, 30 mL Multiple Dose Via

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FOR IMMEDIATE RELEASE - December 20, 2010 - American Regent is conducting a nationwide voluntary recall of the following:

**Dexamethasone Sodium Phosphate Injection, USP, 4 mg/mL, 30 mL Multiple Dose Vial
NDC # 0517-4930-25**

Lot #'s	Exp. Dates
8811	12/2010
9093	02/2011
9195	03/2011
9296	04/2011
9419	06/2011
9505	07/2011
9649	09/2011

PLEASE NOTE: This recall, initiated on December 20, 2010 to the User Level, is for these lots only. No other lots of the 30 mL MDV or other sizes of Dexamethasone Sodium Phosphate Injection, USP, 4 mg/mL, are subject to this recall.

This voluntary recall was initiated because some vials of these lots either contain particulates or have the potential to form particulates prior to their respective expiration dates. American Regent is undertaking this recall in consideration of the potential for safety issues if these lots of product are administered to patients.

The product was distributed to wholesalers and distributors nationwide.

Hospitals, infusion centers, clinics and other healthcare facilities should not use American Regent Inc., Dexamethasone Sodium Phosphate Injection, USP, 4 mg/mL, 30 mL Multiple Dose Vials with the above lot #'s for patient care and should immediately quarantine any product for return.

"Patient safety is our primary concern, and we are committed to taking the necessary steps to protect patients from any potential safety risks," said Mary Jane Helenek, President and CEO of American Regent.

While American Regent continues to investigate this issue, the company is taking precautionary action and initiated this voluntary recall. American Regent has informed the FDA of its actions and is maintaining ongoing discussions with the agency.

As is standard practice, and as stated in the Dexamethasone Sodium Phosphate Injection, USP Product Package Insert, "*Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.*"

American Regent will credit accounts for all returned product with these lot #'s. Those with questions about the return process, please call our Customer Service Department at 1-800-645-1706: Monday thru Friday from 8:30AM to 7:00PM ET.

Hospitals, infusion centers, clinics and healthcare providers, or patients with other questions may contact the Professional Services Department at 800 645-1706.

Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to American Regent, Inc. **via email at PV@luitpold.com, by fax to 610-650-7781 or 610-650-0170 or by phone at 1-800-734-9236.** Adverse reactions may also be reported to

FDA's [MedWatch Adverse Event Reporting program online](#)⁹, or by returning the postage paid [FDA form 3500](#)¹⁰, by mail to [MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or via fax [1-800-FDA-0178] or phone 1-800-332-1088

Dexamethasone Sodium Phosphate Injection, USP is manufactured by Luitpold Pharmaceuticals, Inc. and is distributed by American Regent, Inc. (Shirley, NY).

Source: Luitpold Pharmaceuticals, Inc.

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[Photo: Products Labels](#)¹³

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